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Tennican

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(54) **CATHETER DEVICES AND TECHNIQUES**

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CPC ***A61M 39/162*** (2013.01); ***A01N 59/00*** (2013.01); ***A61K 33/40*** (2013.01); ***A61M 11/08*** (2013.01); ***A61M 15/08*** (2013.01); ***A61M 25/002*** (2013.01); ***A61M 25/0017*** (2013.01); ***A61M 39/20*** (2013.01); *A61K 9/0014* (2013.01); *A61K 47/183* (2013.01); *A61M 35/00* (2013.01); *A61M 39/165* (2013.01); *A61M 2025/0019* (2013.01); *A61M 2205/583* (2013.01); *A61M 2209/06* (2013.01); *F04C 2270/0421* (2013.01); *Y10S 604/905* (2013.01)

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USPC 604/246, 263, 533, 544; 206/210, 364, 206/571; 15/97.1; 134/6
See application file for complete search history.

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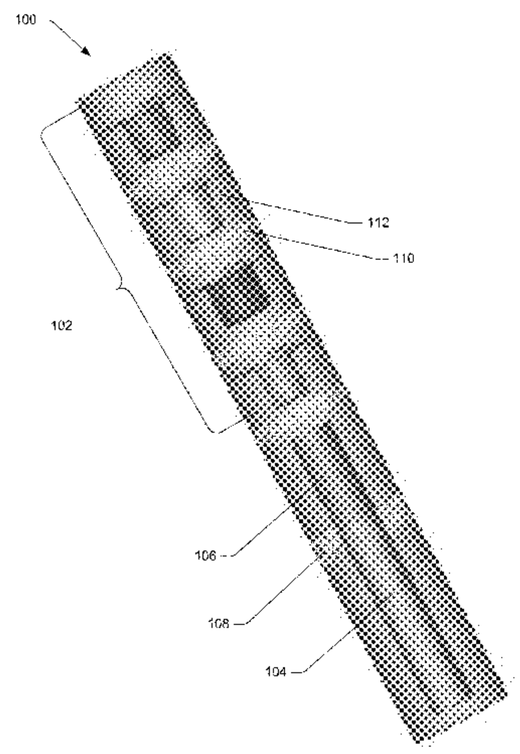
(57) **ABSTRACT**

This application describes example antimicrobial compositions that may be used alone or in combination with catheters and catheter insertion sites. According to another aspect, the application describes catheters which may employ one or more protection devices, such as cleaning caps, protective caps or both.

20 Claims, 3 Drawing Sheets



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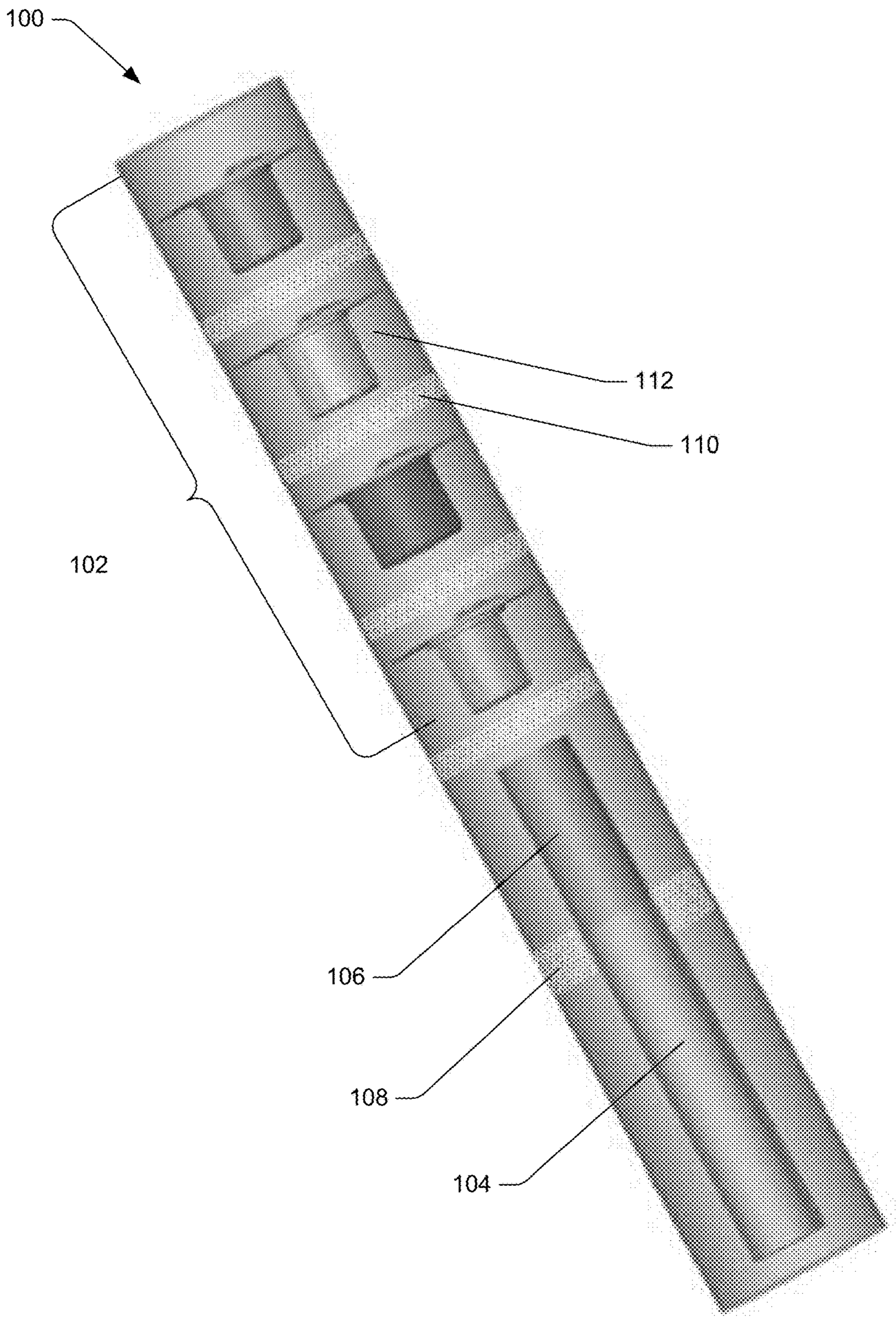

FIG. 1

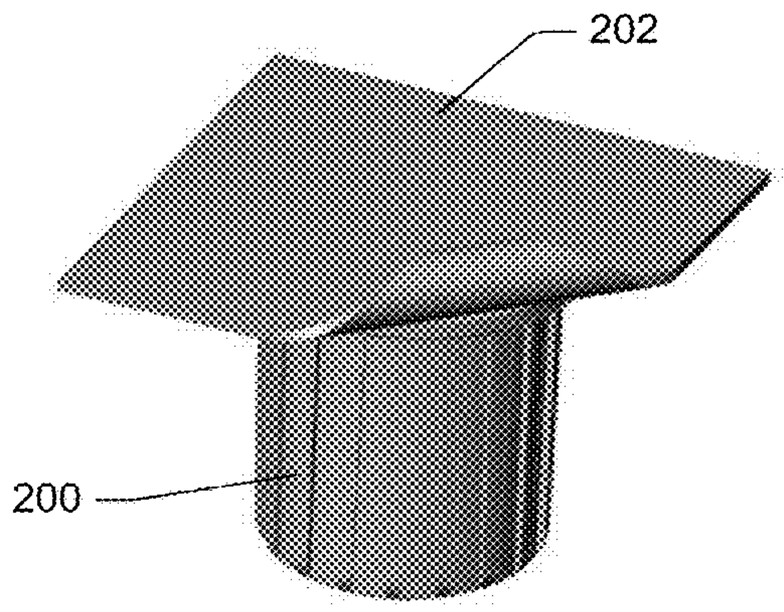

FIG. 2A

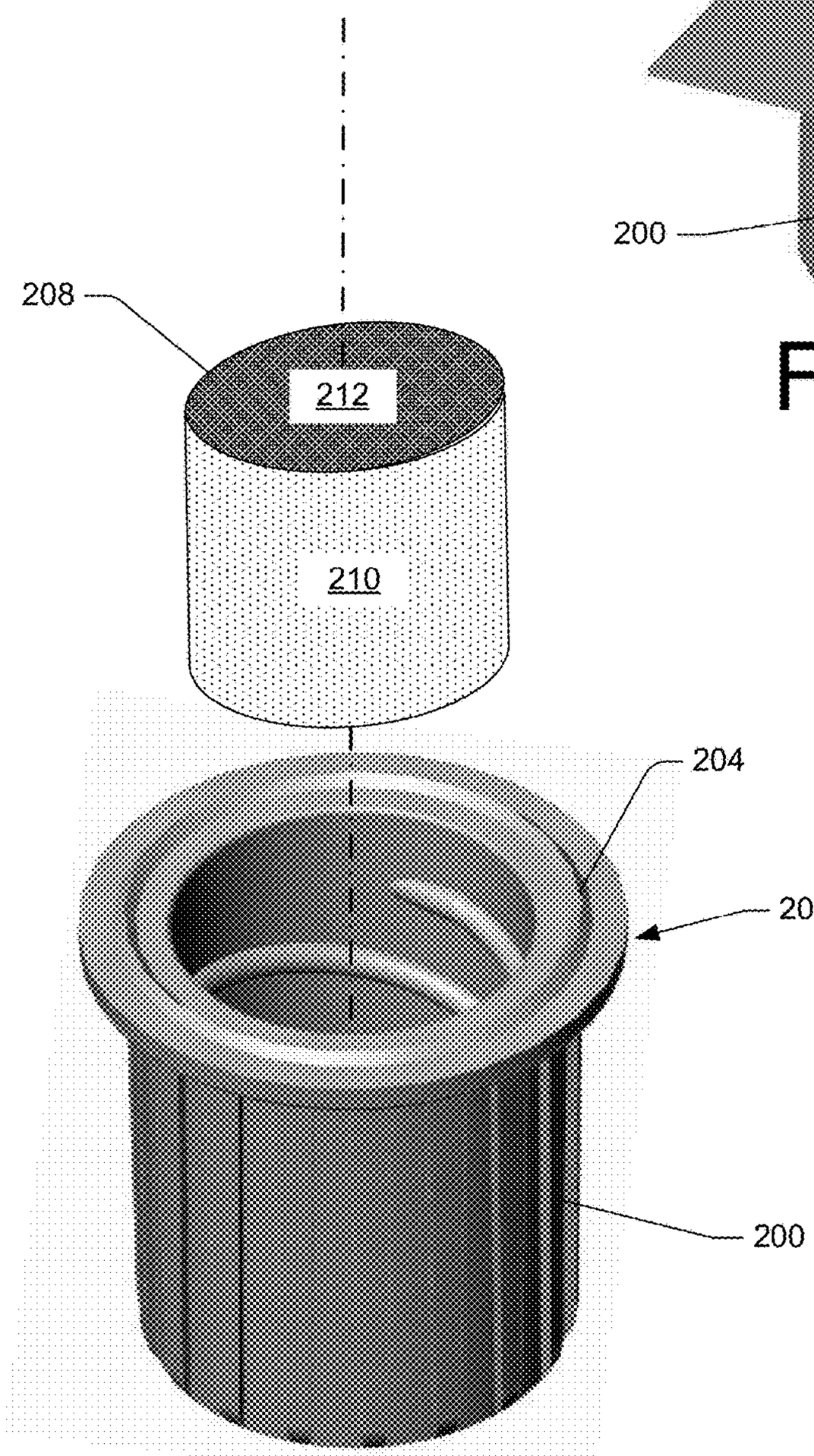

FIG. 2B

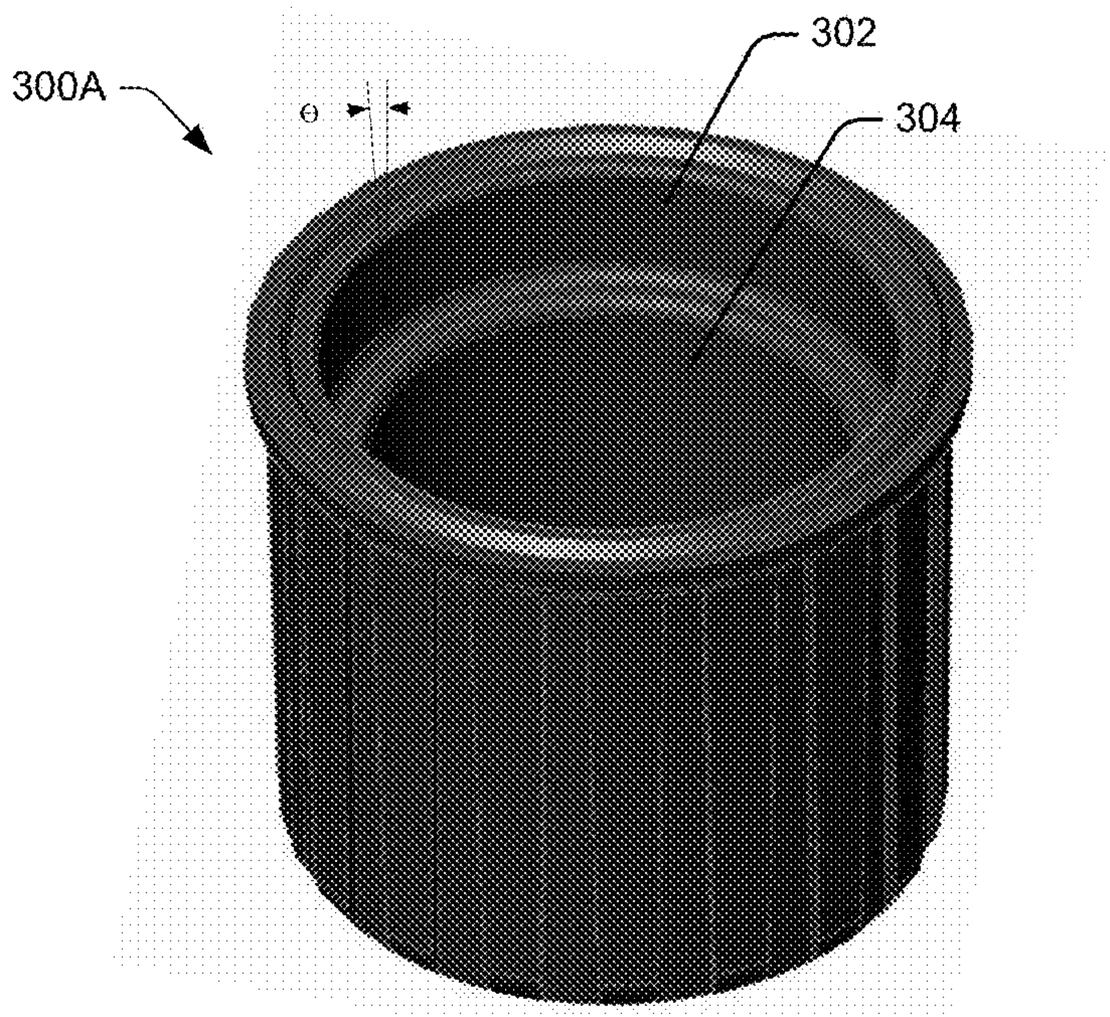

FIG. 3A

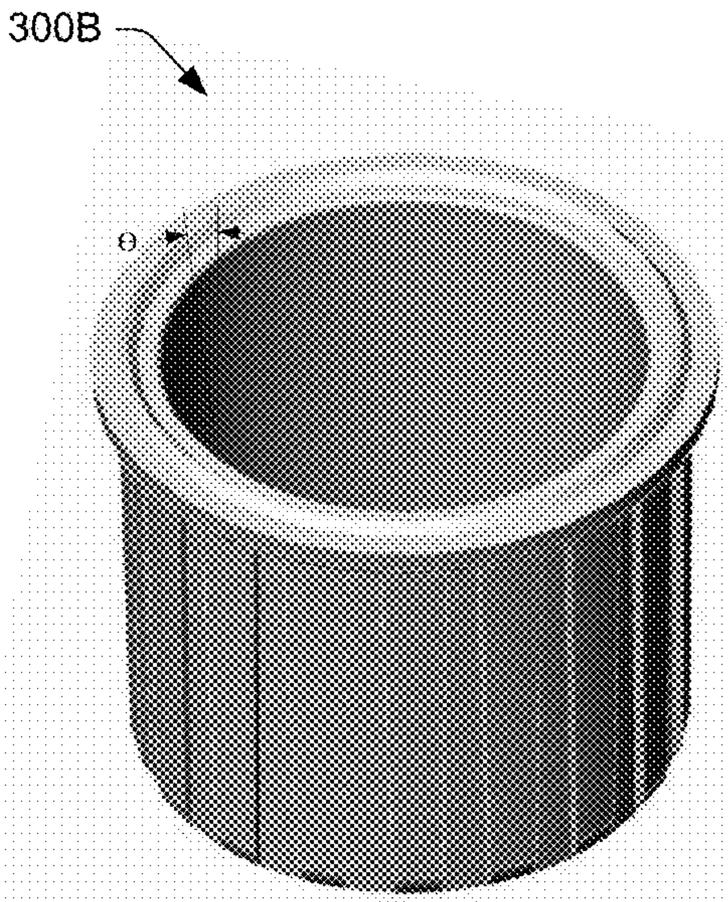

FIG. 3B

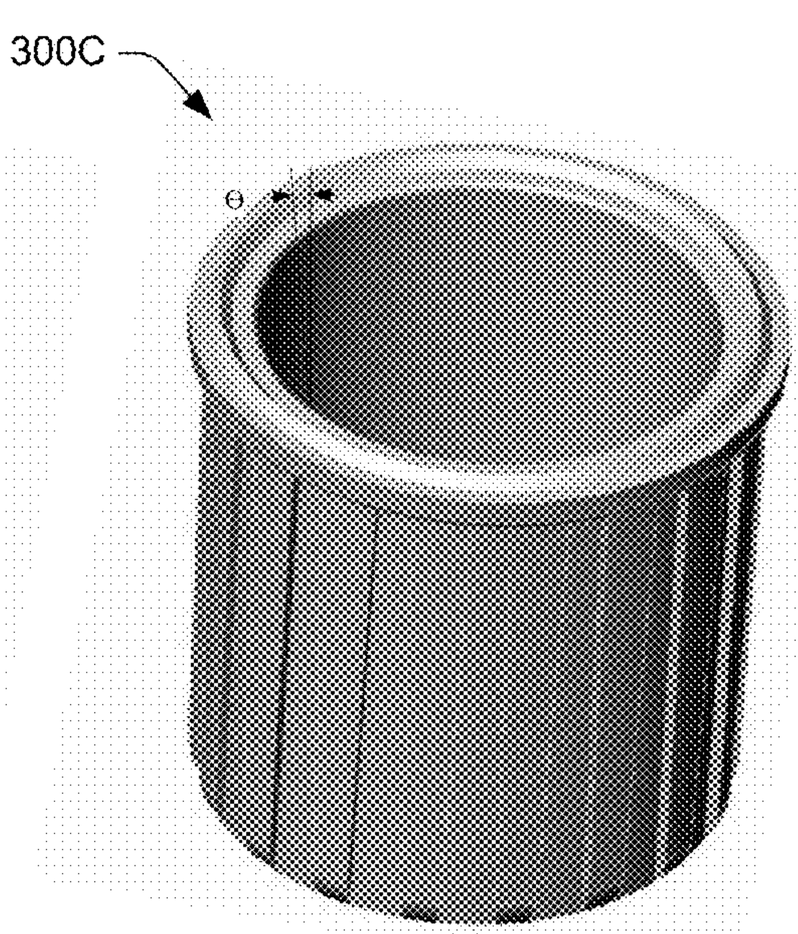

FIG. 3C

CATHETER DEVICES AND TECHNIQUES

CROSS REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Patent Application No. 61/564,206 filed on Nov. 28, 2011, entitled "Medical Devices and Techniques for Antiseptic, Immunomodulatory and Antineoplastic Therapies," which is hereby incorporated by reference in its entirety.

BACKGROUND

Infection remains a real problem in the medical industry today. Infections are often caused by contamination of intravascular (IV) lines (e.g., intravenous, intra-arterial, etc.), contamination of an injection site or blood draw site (e.g., from a vein, artery, or capillary), urinary catheters, wound sites, incision sites, and numerous other sources of infection in healthcare facilities. For example, in the United States alone, central venous catheters cause an estimated 80,000 catheter-related blood stream infections per year, which result in up to 28,000 deaths among patients in intensive care units. O'Grady N P, Alexander M, Dellinger E P, et al., *Guidelines for the prevention of intravascular catheter-related infections*. MMWR Recomm Rep 2002; 51:1-29. These numbers do not include infections caused by contamination of injection sites, blood draw sites, catheters, or any of the other numerous sources of contamination in healthcare facilities. Infection is even more of a problem in developing nations, where syringes, IV lines, and other equipment are routinely used and re-used for multiple different patients.

BRIEF SUMMARY OF THE INVENTION

This application describes approaches to reducing and/or preventing infections. In one aspect, the application describes example antimicrobial compositions that may be used alone or in combination with catheters and catheter insertion sites. According to another aspect, the application describes catheters which may employ one or more protection devices, such as cleaning caps, protective caps or both. This summary is not intended to identify essential features of the claimed subject matter, nor should it be used to limit the scope of the claims.

A first embodiment of the invention concerns a catheter assembly comprising a package containing a catheter and at least one cleaning device. The cleaning device may be a cleaning cap, a protective cap or both. Moreover, the catheter may have at least one port.

Another embodiment concerns a method for obtaining a urine specimen comprising providing a catheter assembly, the catheter assembly comprising a package containing a catheter and at least one cleaning cap, wherein the catheter has at least one port; opening the package to remove the cleaning cap; installing the catheter at a urological catheter insertion site; cleaning said port with a port cleaning device; and obtaining a urine sample via the port. The catheter and at least one cleaning cap are individually sealed in separate compartments of the package.

Yet another embodiment concerns a method for administering an antimicrobial composition to a urological site comprising providing a catheter assembly, the catheter assembly comprising a package containing a catheter and at least one cleaning cap, wherein the catheter has at least one port; opening the package to remove the cleaning cap; installing a catheter at a urological catheter insertion site, said catheter having at least one port; cleaning said port with a port cleaning device; and administering an antimicrobial composition via the port. The catheter and at least one cleaning cap are individually sealed in separate compartments of the package.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows a catheter assembly;

FIGS. **2**A and **2**B show details of an example cleaning device; and

FIG. **3**A-**3**C show details of several example cleaning devices.

DETAILED DESCRIPTION

FIG. **1** illustrates an example of a catheter device and assembly which may, but need not necessarily, be used in connection with the antimicrobial compositions described herein. When used with the antimicrobial compositions described herein, however, the catheter device may provide disinfecting and/or therapeutic effects.

As shown in FIG. **1**, a package **100** including one or more different site cleaning devices **102** coupled together with a catheter **104**. The package **100** may comprise transparent, flexible, polymeric packaging allowing the user to see and inspect the contents of the package prior to use. The cleaning devices **102** and the catheter **104** may be individually sealed in separate compartments **112** of the package **100**, wherein each compartment **112** is separated from an adjacent compartment **112** by a partition **110**, or they may be sealed together in a common compartment **112** of the package. The cleaning devices **102** may be used to clean a catheter insertion site prior to insertion of the catheter **104**. According to an embodiment, the cleaning device can be a piece of material such as a piece of cloth, swab, or sponge. According to an embodiment, the cleaning devices **102** may be cleaning caps, protective caps or both as further described below.

The catheter **104** may comprise a urinary catheter or any other type of catheter. In the case where the catheter **104** is a urinary catheter, the catheter may be either a Foley type, longer use, or a simple, straight, single use catheter. In either case, the catheter **104** would include an antimicrobial gel lubricant **106** applied to and/or contained at a tip area compartment of the package **100**. The package **100** may include a restrictor **108** (e.g., a portion of the package fused closely to an exterior of the catheter midway along the length of the catheter) to prevent the gel lubricant from covering the whole exterior of the catheter **104**. The one or more cleaning devices **102** being disposed in one or more compartments **112** ahead of the tip of the catheter **104**, serve as a reminder to the user to clean and sanitize the catheter insertion site prior to insertion of the catheter. Once the site is cleaned, the catheter **104** may be inserted by peeling back the package **100** to expose the tip end of the catheter and holding the catheter via the package **100**. In this way, the user need not even touch the catheter **104** during insertion, providing a "No Touch Cath" technique which even further reduces the risk of contamination and infection.

Additionally, in some embodiments, the lumen of the catheter **104** could be pre-filled with an antimicrobial composition such as those described herein.

Once the catheter **104** is installed, in some embodiments, the catheter may be used to obtain sterile, uncontaminated urine specimens via a urological catheter port. In that case, port cleaning and protection devices may be used to clean

and protect the catheter port. The catheter port caps may use the same or different antimicrobial compositions than those used for the IV port cleaning and protective caps.

FIGS. **2**A, **2**B, and **3**A-**3**C illustrate details of several example port cleaning and protective caps. Each of the caps may be made of materials such as, but not limited to, polyethylene, polypropylene, and/or copolymer materials. The caps may also comprise a material or agent that is UV protective to preserve the integrity of hydrogen peroxide during storage, shipping, etc. The caps themselves may additionally or alternatively be housed in a packaging that contains UV protective materials to inhibit breakdown of the hydrogen peroxide.

FIGS. **2**A and **2**B illustrate an example of an IV port protective cap **200** designed to thread onto a threaded port, such as a female Luer® connector, to provide a physical barrier against recontamination. As shown in FIG. **2**A, the protective cap **200** is hermetically sealed by a protective cover **202**. The protective cover **202** may be removably fused or bonded to the protective cap **200** by sonic welding, microwave welding, thermal fusion, or other bonding techniques. The protective cover **202** may be made of a same or different material than the protective cap **200**. To facilitate the sealing of the protective cover **202** to the protective cap **200**, as shown in FIG. **2**B, the protective cap includes an energy director **204** disposed on a top surface of a rim **206** or flange surrounding an opening of the protective cap **200**. The energy director **204** comprises a raised ridge or rib of material having a small cross section relative to the rim **206** of the protective cap **200**. The small cross section of the energy director **204** allows the energy director to melt more quickly and to fuse with the protective cover **202** with less energy than that required to melt the entire rim **206** of the protective cap **200**. The energy director **204** also allows the protective cover **202** to fuse to the protective cap **200** over a relatively thin region, thereby making the protective cover **202** easier to remove from the protective cap **200** than if it were fused over the entire area of the rim **206** of the protective cap **200**.

The rim **206** is designed as a "no touch rim," which extends radially from the perimeter of the main body of the protective cap **200**, thereby minimizing a likelihood that a user's fingers will come in contact with the internal surfaces of the protective cap during use. In the illustrated embodiment, the energy director **204** is disposed radially outward of an opening of the protective cap, but inward of an outer edge of the rim **206**. This ensures that the portion of the rim **206** inside the energy director **204** remains sterile prior to use. The no touch rim **206** increases the likelihood that the portion of the rim **206** inside the energy director **204** remains sterile even during use. In other embodiments, the energy director may be disposed anywhere on the rim **206** (e.g., centrally as shown, at an inner perimeter of the rim proximate the opening, or at an outer perimeter of the rim).

As shown in FIG. **2**B, the protective cap **200** also includes an applicator material **208** (shown in exploded view in this figure for clarity). In the illustrated example, the applicator material comprises a cylindrical foam material having an open cell region **210** around the circumference of the sides of the cylinder and a closed cell region **212** on one or both axial ends of the cylinder. The open cell region **210** allows the applicator material **208** to absorb and carry an antimicrobial composition, such as those described above. The closed cell region **212** serves to at least partially cover and seal an end of an IV port to prevent the IV port from leaking and to prevent substantial amounts of the antimicrobial composition from entering the IV port. Both the open cell region **210** and the closed cell region **212** may have a certain amount of texture or roughness to scrub the IV port.

Also, while applicator material **208** is illustrated as being a generally cylindrical body, in other embodiments, the applicator material may take on other shapes and/or sizes. Further, the applicator material **208** may include different surface treatments (e.g., siping, slitting, etc.), surface finishes (e.g., macro-, micro-, or nano-structures, etc.), and/or contours (e.g., rounded, ribbed, protrusions, fingers, etc.).

FIGS. **3**A-**3**C illustrate several variations of IV port protective caps **300**A, **300**B, and **300**C, respectively (collectively referred to as protective caps **300**), for use with IV port connectors of varying outer diameter (OD), such as male Luer® connectors. The protective caps **300** of these embodiment are slip fit caps, in that they are designed to slip over and fit securely on IV port connectors of varying OD, since not all port connectors have standardize OD.

FIG. **3**A illustrates a protective cap **300**A having a stepped inner surface, including a first inner surface **302** and a second inner surface **304**, the second inner surface **304** having a smaller average diameter than the first inner surface. The first and second inner surfaces **302** and **304** may have diameters chosen to match ODs of common ports on the market, of maximum and minimum ODs of ports on the market, or based on other criteria. Further both of the first and second inner surfaces **302** and **304** may be tapered (i.e., have a draft angle θ), such that a diameter of the first and second inner surfaces is largest closest to an opening of the protective cap **300**A and decreases toward the bottom, closed end of the protective cap. A draft angle of the first inner surface **302** may be the same as, greater than, or less than a draft angle of the second inner surface **304**. When the protective cap **300**A is placed on an IV port, the protective cap **300**A will slide over the IV port until an OD of the IV port contacts and seals against the interior surface of the protective cap **300**A at either the first inner diameter **302** (in the case of an IV port with a relatively large OD) or the second inner diameter **304** (in the case of an IV port with a relatively small OD).

FIGS. **3**B and **3**C illustrate alternative embodiments of slip fit protective caps **300**B and **300**C, respectively, which have continuous, smooth inner surfaces. Rather than being stepped as in the embodiment of FIG. **3**A, the protective caps **300**B and **300**C have continuous, smooth inner surfaces. Like the inner surfaces of the stepped protective cap **300**, the inner surfaces of the protective caps **300**B and **300**C are tapered to accommodate IV ports of varying OD. However, in order to accommodate IV ports having a wide range of ODs, the draft angle θ of the protective caps needs to be larger (i.e., a more pronounced taper) as in the case of protective cap **300**B, and/or the protective cap needs to be made deeper, as in the case of protective cap **300**C.

Additional details of example IV port cleaning and protective devices may be found in U.S. patent application Ser. No. 11/745,843, filed May 8, 2007, to Tennican, which is incorporated herein by reference.

Additionally or alternatively, a flush syringe could be used to introduce a flush solution to flush the catheter lumen, bladder, ureter, renal pelvis, or other portions of the urinary tract. The flush solutions used may vary depending on the site to which it is to be delivered, e.g., catheter lumen, bladder, ureter, renal pelvis. In some examples, liquid antimicrobial compositions such as those described herein may be used as the flush solution.

According to an embodiment, the catheter assembly includes an antimicrobial composition. Exemplary antimicrobial compositions that may be used in connection with

the approaches described herein may include those described in, for example, U.S. patent application Ser. No. 12/874,188, filed Sep. 1, 2010, to Tennican et al., which is incorporated herein by reference. In that case, the antimicrobial compositions may include water (H_2O), a strong and non-toxic chelating agent such as ethylenediaminetetraacetic acid (EDTA)(e.g., disodium EDTA, calcium disodium EDTA, magnesium EDTA, gallium EDTA) or sodium citrate (or acids, salts, derivatives, or other forms of EDTA or sodium citrate), a short-chain monohydric alcohol (e.g., ethanol with a molecular formula of C_2H_5OH and an empirical formula of C_2H_6O), and a strong, small molecule oxidizing agent such as hydrogen peroxide (H_2O_2). In one specific example, the compositions may consist essentially of water, EDTA, ethanol, and hydrogen peroxide. However, in other examples, other antimicrobial compositions may be used in combination with the devices described in this application.

The antimicrobial compositions may be in a liquid form or a gel form, and may be combined with one or more carriers or diluents, depending on the needs of a specific application. For example, in applications in which the antimicrobial composition is used as a hand sanitizer, the antimicrobial composition may be in a gel. As another example, if the antimicrobial composition is used as a cleaning agent, a flush solution, or an irritant, the antimicrobial composition may be in a liquid form. In that case, the concentration of the various constituents may depend on, for example, a desired level of disinfection, whether the composition is being applied directly to living tissue or to a medical device, and/or to avoid irritation of tissue to which the composition will be applied directly or indirectly (e.g., via a medical device to which the composition is or was applied). In yet another example, the antimicrobial compositions may include or be combined with a lubricant (e.g., glycerin), surfactant or emulsifier (e.g., glycerol monolaurate (GML)), or the like and may be applied to a catheter, tracheal tube, scope, instrument, or other device that is to be inserted into a patient's body.

In other embodiments, for therapeutic treatment of localized infections and/or pre-malignant and malignant lesions in the urethra, bladder, ureter, renal pelvis, antimicrobial compositions such as those described herein may be delivered through a catheter or via direct observations via a cystoscope or ureteroscope or nephrostomy scope.

In still other embodiments, the antimicrobial compositions such as those described herein may be used as an irrigant to flush a catheter to prevent the buildup of biofilms and/or to break up the formation of stones.

Although the application describes embodiments having specific structural features and/or methodological acts, it is to be understood that the claims are not necessarily limited to the specific features or acts described. Rather, the specific features and acts are merely illustrative some embodiments that fall within the scope of the claims of the application.

What is claimed is:

1. A catheter assembly comprising:

a single sealed package containing at least a first individually sealed compartment, a second individually sealed compartment, and a third individually sealed compartment, the respective individually sealed compartments separated from each other by partitions,

wherein the first individually sealed compartment contains a catheter having a tip and at least one port,

wherein the second individually sealed compartment contains a cleaning device used to clean a catheter insertion site prior to insertion of the catheter,

wherein the third individually sealed compartment contains a protective cap,

and

wherein the second individually sealed compartment and the third individually sealed compartment are disposed ahead of and adjacent to the tip of the catheter.

2. The catheter assembly according to claim **1**, wherein the package is transparent.

3. The catheter assembly according to claim **1**, wherein the catheter is a urinary catheter.

4. The catheter assembly according to claim **1**, wherein the package further includes an antimicrobial gel lubricant applied to and/or contained in proximity to the tip of the catheter.

5. The catheter assembly according to claim **4**, wherein a portion of the package is fused closely to an exterior of the catheter midway along the length of the catheter to prevent the antimicrobial gel lubricant from migrating away from the tip and covering another area of the catheter.

6. The catheter assembly according to claim **1**, wherein at least a portion of an inside of the catheter contains an antimicrobial composition.

7. The catheter assembly according to claim **1**, further comprising an applicator material.

8. The catheter assembly according to claim **7**, wherein the applicator material includes an antimicrobial composition.

9. A method for using a catheter comprising:

obtaining a catheter assembly, the catheter assembly comprising a single sealed package containing a catheter having a tip and at least one port, a cleaning device, and a port cleaning cap, wherein the catheter, the cleaning device, and the port cleaning cap are individually sealed in separate compartments of the package and each of the separate compartments is separated from an adjacent compartment by a partition;

opening the package to remove the cleaning device;

cleaning the catheter insertion site with the cleaning device;

installing the catheter at the catheter insertion site;

opening the package to remove the port cleaning cap; and

cleaning said port with the port cleaning cap.

10. The method according to claim **9**, wherein the package also contains at least one protective cap and the method further comprising covering the port with the protective cap.

11. The method according to claim **9**, wherein the package further includes an antimicrobial gel lubricant applied to and/or contained in proximity to the tip of the catheter.

12. The method according to claim **11**, wherein a portion of the package is fused closely to an exterior of the catheter midway along the length of the catheter to prevent the antimicrobial gel lubricant from migrating away from the tip area and covering another area of the catheter.

13. The method according to claim **9**, further comprising an applicator material contained within the port cleaning cap.

14. The method according to claim **13**, wherein the applicator material includes an antimicrobial composition.

15. The method according to claim **9**, further comprising obtaining a sample via the port.

16. The method according to claim **9**, wherein catheter assembly is configured with the separate compartment containing the cleaning device and the separate compartment containing the port cleaning cap disposed ahead of and adjacent to the tip of the catheter.

17. A catheter assembly comprising a single sealed package containing a catheter and a plurality of cleaning devices,

wherein the plurality of cleaning devices include at least two of: a cleaning device used to clean a catheter insertion site prior to insertion of the catheter, a port cleaning cap, or a protective cap,

wherein the catheter and each of the cleaning devices are individually sealed in separate compartments of the package and said cleaning devices are disposed in the separate compartments ahead of and adjacent to a tip of the catheter, and

wherein each separate compartment is separated from an adjacent compartment by a partition.

18. The catheter assembly according to claim **17**, further comprising an applicator material contained within the port cleaning cap.

19. The catheter assembly according to claim **18**, wherein the applicator material includes an antimicrobial composition.

20. The catheter assembly according to claim **19**, wherein the antimicrobial composition comprises water, a chelating agent, a short-chain monohydric alcohol, and hydrogen peroxide.

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